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10/559,533	12/02/2005	Tadashi Okiyama	061639-0318680	9144

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PILLSBURY WINTHROP SHAW PITTMAN, LLP
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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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08/11/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/559,533	Applicant(s) OKIYAMA, TADASHI	
	Examiner SHEFALI PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-11,15-19,21,22 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,15,16,21,22 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. In the reply, filed on June 8, 2011, Applicant amended claims 1, 2, 15, 21, and 25-27.
2. In the non-final rejection of February 15, 2011, Examiner objected to claim 2 for not further limiting the subject matter of claim 1 by reciting "an inner cavity" already recited in claim 1. Applicant amended claim 2. Objection is withdrawn.
3. Examiner rejected claims 1, 15, and 21 under 35 USC 112, 1st paragraph, for an enablement issue with respect to limitation of an exposed back surface of the septum. Applicant amended claims 1, 15, and 21. Rejection is withdrawn.
4. Examiner rejected claims 1, 15, and 21 under 35 USC 112, 2nd paragraph, as the limitation of an exposed back surface of the septum was unclear. Applicant amended claims 1, 15, and 21. Rejection is withdrawn.
5. Examiner rejected claims 15 and 21 under 35 USC 112, 2nd paragraph, for insufficient antecedent basis for the term "the annular protrusion". Applicant amended claims 15 and 21. Rejection is withdrawn.
6. Examiner stated that the incorrect status identifier of (Cancelled – Previously Presented) was given to claim 2. Applicant amended the status identifier of claim 2 to be (Currently Amended). The amendment is now compliant.
7. Currently, claims 1-5, 7, 15, 16, 21, 22, and 25-27 are under examination.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regards to claim 2, after amendment, the claim now recites that "the inner cavity is deformed by the insertion of the tube member so as to accommodate the septum". The specification does not describe an inner cavity that can be deformed, and therefore, the new limitation comprises new matter.

10. Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In regards to claims 25-27, after amendment, the claims now recite that "the back surface of the septum contacts the first fluid". The disclosure of elected Figures 2-5, specifically in reference to Figure 4, only shows that the first fluid contacts the slit surface of the septum, not the back surface of the septum, and thus creating an enablement issue.

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11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 2, after amendment, the claim now recites that "the inner cavity is deformed by the insertion of the tube member so as to accommodate the septum". It is unclear how an inner cavity can be deformed since a cavity is just a hollow space.

In regards to claims 25-27, the claims recite the limitation "the back surface". There is insufficient antecedent basis for this limitation in the claims, since "a back surface" has not been previously introduced in each of claims 25, 26, and 27, or in each of respective prior claims 1, 15, and 21.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 2, 4, 7, 15, 21, 22, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jepson et al (US 6,193,697), and further in view of Vedder (US 5,441,487).

In regards to claim 1, Jepson et al teaches a mixture injection port (Figures 3, 4A, and 4B) comprising:

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- a. a channel tube unit (pre-slit injection site [34]) including a body portion (housing [40]) that is provided with an inner cavity and a leg portion (fluid flow member [46]) that is provided with a narrow tube portion having a smaller width than that of the inner cavity
- b. a septum (septum [52]) covering one end of the channel tube unit and having a slit (opening [66]) into which a tube member is inserted

Jepson et al does not teach a circulating member provided in the channel tube unit below the septum, the circulating member being separate from the channel tube unit. Vedder teaches a mixture injection port (Figures 1-4) with a circulating member (disc valve [14]) that is separate from a channel tube unit (medical site [10]). The circulating member [14] comprises a plate portion (disc [28]) arranged to change direction of flow of a first fluid injected from the inserted tube member or a second fluid flowing from the other end of the channel tube unit and an edge portion (actuator [26]) that protrudes upwardly towards the septum from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Jepson et al, with a circulating member, as taught by Vedder, as the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

In regards to claim 2, in a modified port of Jepson et al and Vedder, Jepson et al teaches that the body portion [40] includes an opening that is covered by the septum [52] and the inner

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cavity is deformed by the insertion of the tube member so as to accommodate the septum and wherein the narrow tube portion [46] is configured to provide communication between the inner cavity and the other end of the channel tube (Figure 3).

In regards to claim 4, in a modified port of Jepson et al and Vedder, Jepson does not teach a plate portion. Vedder teaches that the plate portion [28] of the circulating member is provided with a holding portion (nipple [32]) on its back face that is engaged with the narrow tube portion and holds the circulating member inside the channel tube (Figure 1). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Jepson et al and Vedder, with a holding portion, as taught by Vedder, as the holding portion will provide a seat for the plate portion in engagement of the portion of the port containing the narrow tube portion (column 3, lines 43-46).

In regards to claim 7, in a modified port of Jepson et al and Vedder, Jepson does not teach a circulating member. Vedder teaches a groove (opening through interior [36]) for guiding the first fluid or the second fluid that is formed on an inner circumferential surface and an outer circumferential surface of the edge portion [26]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the modified port of Jepson et al and Vedder, with a groove, as taught by Vedder, as the groove of the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

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In regards to claim 15, Jepson et al teaches a mixture injection port (Figures 3, 4A, and 4B) comprising:

- a. a channel tube unit (pre-slit injection site [34]) including a body portion (housing [40]) that is provided with an inner cavity and a leg portion (fluid flow member [46]) that is provided with a narrow tube portion having a smaller width than that of the inner cavity
- b. a septum (septum [52]) covering one end of the channel tube unit and having a slit (opening [66]) into which a tube member is inserted

Jepson et al does not teach a circulating member provided in the channel tube unit below the septum, the circulating member being separate from the channel tube unit. Vedder teaches a mixture injection port (Figures 1-4) with a circulating member (disc valve [14]) that is separate from a channel tube unit (medical site [10]). The circulating member [14] comprises a plate portion (disc [28]) arranged to change direction of flow of a first fluid injected from the inserted tube member or a second fluid flowing from the other end of the channel tube unit and an edge portion (actuator [26]) that protrudes upwardly towards the septum from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Jepson et al, with a circulating member, as taught by Vedder, as the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

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In regards to claims 21 and 22, Jepson et al teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 3, 4A, and 4B), the mixture injection port comprising a channel tube unit [34] including a body portion [40] that is provided with an inner cavity and a leg portion [46] that is provided with a narrow tube portion having a smaller width than that of the inner cavity and a septum [52] covering one end of the channel tube unit and having a slit [66], the method comprising:

- a. inserting a tube member (piercing member [98]) into the slit (Figures 4A-4B)
- b. injecting a first fluid into the tube member or a second fluid into an other end of the channel tube unit (column 8, lines 46-59)
- c. circulating the first fluid or the second fluid towards the septum side (column 8, lines 46-59)
- d. guiding the first fluid to the other end of the channel tube unit below the septum or the second fluid to a top portion of the tube member (column 8, lines 46-59)

Jepson et al does not teach a circulating member provided in the channel tube unit below the septum, the circulating member being separate from the channel tube unit. Vedder teaches a mixture injection port (Figures 1-4) with a circulating member (disc valve [14]) that is separate from a channel tube unit (medical site [10]). The circulating member [14] comprises a plate portion (disc [28]) arranged to change direction of flow of a first fluid injected from the inserted tube member or a second fluid flowing from the other end of the channel tube unit and an edge portion (actuator [26]) that protrudes upwardly towards the septum from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the

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port/method, of Jepson et al, with a circulating member, as taught by Vedder, as the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

In regards to claims 25-27, in modified port/method of Jepson et al and Vedder, Jepson et al teaches that at least a portion of the back surface of the septum [52] contacts the first fluid when the septum is deformed by the insertion of the tube member (Figures 3 and 4B).

15. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jepson et al and Vedder, as applied to claims 2 and 15 above, and further in view of Cote (US 5,775,671).

In regards to claim 3, in a modified port of Jepson et al and Vedder, Jepson et al does not teach a plate portion. Vedder does not teach a groove that is formed on a surface on the inner cavity side of the plate portion of the circulating member, the groove extending in a direction different from a direction from which the first fluid is injected from the inserted tube member, and wherein the first fluid is allowed to flow along the groove so that the direction of flow of the first fluid is changed. Cote teaches a mixture injection port (Figures 1, 2A, 3, and 4) with a groove (spaces in between raised areas [58]) that is formed on a surface on the inner cavity side of a plate portion (transverse wall [60]) of a circulating member (actuator [50]), the groove extending in a direction different from a direction from which the first fluid is injected from an inserted tube member. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Jepson et al

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and Vedder, with a groove, as taught by Cote, as the groove of the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 1- 9)(column 5, lines 23-40).

In regards to claim 16, in a modified port of Jepson et al and Vedder, Jepson et al does not teach a circulating member. Vedder teaches a groove (opening through interior [36]) that is formed on a surface of the edge portion [26] of the circulating member and the first fluid flows along the groove towards the septum side. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the modified port of Jepson et al and Vedder, with a groove, as taught by Vedder, as the groove of the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44). However, Vedder does not teach another groove that is formed on a surface of the plate portion [28] of the circulating member and the first fluid flows along the another groove towards the edge portion. Cote teaches a mixture injection port (Figures 1, 2A, 3, and 4) with a groove (spaces in between raised areas [58]) that is formed on a surface of a plate portion (transverse wall [60]) of a circulating member (actuator [50]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Jepson et al and Vedder, with another groove, as taught by Cote, as the another groove of the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass

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through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 1- 9)(column 5, lines 23-40).

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jepson et al and Vedder, as applied to claim 4 above, and further in view of Arnett (US 5,817,069).

In regards to claim 5, in a modified port of Jepson et al and Vedder, Jepson et al does not teach a plate portion. Vedder teaches a plate portion and a holding portion; however, Vedder does not teach a groove for guiding the first fluid or the second fluid that is formed in the back face of the plate portion and the holding portion. Arnett teaches a mixture injection port (Figure 1, assembly [10]) comprising a groove (second fluid passageway [106]; openings [108][110]) of guiding a first fluid or a second fluid that is formed in the back face of a plate portion (actuator [20]) and a holding portion (second actuator end [98] and exterior surface [100]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion and the holding portion, of the modified port of Jepson et al and Vedder, with a groove, as taught by Arnett, as the groove of the plate portion and holding portion will allow fluid to freely flow through the groove from the inlet of the port to the outlet of the port in either direction (column 5, lines 25-32).

Response to Arguments

17. Applicant's arguments filed June 8, 2011, have been fully considered but they are not persuasive:

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In regards to claims 1, 15, and 21, Applicant argues that Examiner fails to address the claim features of “such that at least a portion of the surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate portion” (Reply, pages 13-14). However, even though Examiner does not state said claim features in the rejection, that does not mean that the combination of Jepson et al and Vedder does not teach these claim features. This claim feature is an intended use that is capable of being performed by the combination port/method of Jepson et al and Vedder: A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Jepson et al teaches a portion of a surface of a septum [52] that is capable of being contacted with fluid when a tube member is inserted into the septum (Figure 4B). Vedder teaches a portion of a surface of a septum [48], a first fluid that is redirected by a circulating plate portion [28] since fluid flows in two, opposite directions (column 5, lines 26-44), and thus this first redirected fluid is capable of contacting the surface of the septum.

In regards to claims 1, 15, and 21, Applicant argues that the combination of Jepson et al and Vedder makes no mention or suggestion of using redirected circulating fluid "to substantially flush away any stagnant matter present on said surface of the septum" (Reply, page 15). However, this new claim feature is an intended use that is capable of being performed by the combination port/method of Jepson et al and Vedder: A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior

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art structure is capable of performing the intended use, then it meets the claim. In the combination of Jepson et al and Vedder, the redirected circulating fluid is capable of flowing into stagnant regions associated with the surface of the septum and thus would substantially flush away any stagnant matter present in those stagnant regions. Jepson teaches stagnant regions (i.e. regions where matter can stagnate or collect) associated with the surface of the septum when the tube member is inserted into the septum (Figure 4B).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI PATEL whose telephone number is (571)270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

08/04/2011

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767